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CONFIDENTIAL

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K961847

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Device Name: HEMASHIELD VANTAGE™ Vascular Grafts

Predicate Devices: HEMASHIELD® CARDIOVASCULAR GRAFTS:
HEMASHIELD® MICROVEL® Double Velour Knitted Vascular Grafts
HEMASHIELD® Woven Double Velour Vascular Grafts
[510(k) #K954848, determined substantially equivalent Feb. 1, 1996]

Description of Device: The HEMASHIELD VANTAGE™ Vascular Graft is a woven polyester graft, impregnated with bovine collagen.

Intended Uses: For use in systemic vascular reconstructions, e.g., replacement in the case of aneurysmal or occlusive disease, in the peripheral region. The indications are substantially equivalent to the predicate devices, except for the specification of the region of application (peripheral region) of the devices.

Substantial Equivalence: The HEMASHIELD VANTAGE™ Vascular Graft is substantially equivalent in design, components, materials, intended use and labeling to the currently marketed predicate devices. The modifications in this device compared to the predicate devices are:

- It combines a smooth inner surface and veloured outer surface in the same graft; predicate Meadox grafts have the same inner and outer surface: both surfaces are either smooth or velour.
- Like its predicate devices, it is intended for use in vascular replacement in the case of aneurysmal or occlusive disease; with the exception that this device is intended for application in the peripheral region.
- The labeling is distinct from that for the predicate devices to reflect the above described modifications in this device compared to the predicate devices.

Testing has been performed which demonstrates that in spite of these modifications in the proposed device, the proposed devices are substantially equivalent in safety and performance to the currently marketed predicate devices.

Product Testing: The following testing has been conducted on HEMASHIELD VANTAGE™ Vascular Grafts to demonstrate the equivalency in safety and efficacy of these devices to their currently marketed predicate devices.

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| • Burst Strength | - equivalent to marketed product |
| • Tensile Strength | - equivalent to marketed product |
| • Suture Pull Out | - equivalent to marketed product |
| • Wall Thickness | - equivalent to marketed product |
| • Needle Penetration | - equivalent to marketed product |
| • Crush Resistance | - equivalent to marketed product |
| • Flexural Rigidity | - equivalent to marketed product |
| • Integral Water Permeability | - equivalent to marketed product |
| • Integral Water Permeability under load | - equivalent to marketed product |
| • Strength of Collagen Bonding | - equivalent to marketed product |
| • Shrinkage Temperature | - equivalent to marketed product |
| • Glycerol Content | - equivalent to marketed product |
| • Collagen Content | - equivalent to marketed product |
| • Hydrolytic Stability Testing | - equivalent to marketed product |

Biocompatibility Testing: Testing performed in accordance with ISO 9000 Standards indicates that the HEMASHIELD VANTAGE™ Vascular Grafts fabricated from polyester textile materials and with the same collagen composition and method of manufacture as its predicate devices are safe for their intended use and substantially equivalent in biocompatibility to the currently marketed predicate devices.